

Letter Health Consultation

Public Health Implications of Exposures to
Trichloroethylene at the Albea Americas, Inc. Facility

POHATCONG VALLEY GROUNDWATER CONTAMINATION SUPERFUND SITE
WARREN COUNTY, NEW JERSEY

EPA FACILITY ID: NJD981179047

Prepared by
New Jersey Department of Health

AUGUST 1, 2013

Prepared under a Cooperative Agreement with the
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Agency for Toxic Substances and Disease Registry
Division of Community Health Investigations
Atlanta, Georgia 30333

Health Consultation: A Note of Explanation

An ATSDR health consultation is a verbal or written response from ATSDR to a specific request for information about health risks related to a specific site, a chemical release, or the presence of hazardous material. In order to prevent or mitigate exposures, a consultation may lead to specific actions, such as restricting use of or replacing water supplies; intensifying environmental sampling; restricting site access; or removing the contaminated material.

In addition, consultations may recommend additional public health actions, such as conducting health surveillance activities to evaluate exposure or trends in adverse health outcomes; conducting biological indicators of exposure studies to assess exposure; and providing health education for health care providers and community members. This concludes the health consultation process for this site, unless additional information is obtained by ATSDR which, in the Agency's opinion, indicates a need to revise or append the conclusions previously issued.

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State of New Jersey

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August 1, 2013

Mr. Joseph Rotola
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2890 Woodbridge Avenue
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Mr. Rotola:

At your request, this Letter Health Consultation (LHC) has been completed for the Albea Americas, Inc. (AAI) facility located at 191 State Highway 31, in Washington Borough and Washington Township, Warren County, New Jersey. This LHC provides discussion of public health implications, conclusions, and recommendations concerning past and present employee exposures to trichloroethylene (TCE) in indoor air within this facility. This LHC evaluates exposures prior to several on-going actions that were initiated in late June 2013 to attempt to reduce inhalation exposures to facility employees. The U.S. Environmental Protection Agency (US EPA) has indicated that these actions include installing two vapor intrusion mitigation systems, eliminating the facility use of TCE contaminated water from an on-site production well and converting to public water supply for facility operations.

Statement of Issues

In June 2013, the US EPA requested assistance from the federal Agency for Toxic Substances and Disease Registry (ATSDR) and the New Jersey Department of Health (NJDOH) in the interpretation and public health evaluation of site-related contamination detected during March 2013 vapor intrusion/indoor air investigations conducted under remedial investigation activities overseen by the US EPA at the AAI facility. The facility was formerly owned and operated by a number of entities including American National Can and Pechiney Plastic Packaging Inc. (PPPI), and has been identified by US EPA as a source of groundwater contamination at the Pohatcong Valley Groundwater Contamination Superfund (PVGC) site. The PVGC site is situated within Washington Township, Franklin Township, Greenwich Township and Washington Borough in Warren County. Through a cooperative agreement with the ATSDR, the NJDOH reviewed environmental data through June 2013 and prepared this Health Consultation to determine the public health implications associated with inhalation exposures to TCE in indoor air from the TCE source area of the PVGC site.¹ Additionally, the US EPA asked the ATSDR and NJDOH to assess the health concerns to AAI employees and that we concur with US EPA on their site-specific health goal of 7 micrograms per cubic meter ($\mu\text{g}/\text{m}^3$) of TCE in indoor air to be protective for AAI employees.

¹ The ATSDR and NJDOH understand that additional data after June 2013 has been and will continue to be collected at the AAI facility.

Historical and Current Use of Property

The AAI property has housed a manufacturing facility since 1952 under a variety of owners. From approximately March 1952 to December 1956, the AAI property was owned and operated by Sun Tube Corporation (Sun Tube I), a New Jersey corporation and a wholly-owned subsidiary of Bristol-Myers Squibb Company (BMS) (formerly Bristol-Myers Company). BMS designed and constructed the original manufacturing facility on the AAI property.

From approximately 1956 to 1958, the AAI property was owned and operated by Sun Tube Corporation (Sun Tube II), a Delaware corporation, a successor to Sun Tube I and a wholly-owned subsidiary of American Can Company. From approximately 1958 to 1986, the AAI property was owned and operated by American Can Company. From approximately 1987 to 1998, the property was owned and operated by ANC. From 1998 to 2010, the property was owned and operated by PPPI. From 2010 to present, the property has been owned and operated by Albea Americas, Inc. (formerly known as Twist Beauty Packaging US, Inc.), which purchased the property from PPPI in 2010.

Prior to the current plastic packaging operations, operations at the AAI property consisted of the manufacture of aluminum tubes and cans. Hazardous waste, in the form of spent solvents, was generated from the production process, including the cleaning of various products and equipment. TCE was utilized as a degreaser during the manufacturing process.

The two-story facility is approximately 350,000 square feet in size. The ground floor consists of a production area, a former molding department located in the most southwestern portion of the facility, offices, a cafeteria, utility rooms, storage/warehousing, shop areas, and restrooms. The second floor of the facility houses administrative offices, storage areas, and restrooms.

Demographics

No one currently lives on the AAI property. There are approximately 250 employees that work within all areas of the AAI facility. The facility operates at 24 hours a day for 6 days per week. The maximum work shift for employees at the AAI facility is 12 hours per day for 4 days per week for a maximum of approximately 48 hours per week. In the past, the facility used to operate 24 hours a day for 7 days per week.

Environmental Contamination

The US EPA has divided the site investigation of the PVGC site into three operable units known as Operable Unit 1 (OU1), Operable Unit 2 (OU2) and Operable Unit 3 (OU3). OU1 and OU2 address groundwater contaminated with TCE and/or tetrachloroethylene (PCE). The Operable Unit 3 (OU3) study area is located within the borough of Washington and specifically focuses on the source areas believed to be contributing to predominant TCE contamination within groundwater.

The US EPA has conducted vapor intrusion (VI) sampling throughout the OU1 and OU2 study areas from 2006 to present. VI sampling included, but was not limited to, residential properties, public schools and daycare facilities. A number of these sampled properties are located downgradient, and in the vicinity of AAI. Widespread elevated indoor air levels of VOCs were not observed in the OU1 and OU2 study area. Limited VI issues in the OU1 and OU2 study area were addressed via the installation of mitigation systems at three properties. As part of OU3 remedial investigation requirements, a vapor intrusion investigation of the AAI facility was initiated in March 2013 by CDM Smith, the US EPA's OU3 Remedial Investigation/Feasibility Study Contractor.

Soil Gas Assessment

A summary of soil gas results collected below the AAI facility by US EPA contractor CDM Smith, on March 27, 2013 are presented in Table 1 below. A total of 11 soil gas samples, including one duplicate, were collected over a 24-hour period via Summa canisters. Samples were analyzed using US EPA Method TO-15. Soil gas data indicate there is significant TCE contamination below the facility acting as a source of vapor intrusion to the interior of the facility. Detection limits for the majority of TO-15 compounds exceeded the NJDEP Non-Residential Soil Gas Screening Values, particularly for the former molding department area. Therefore, based on the elevated detection limits for these TO-15 compounds, it could not be determined whether they exceeded the NJDEP Non-Residential Soil Gas Screening Values.

**Table 1: Summary of Soil Gas Contaminant Concentrations Exceeding
Environmental Comparison Values – March 2013
Albea Americas, Inc. Facility
191 State Highway 31, Washington Township, Warren County, New Jersey**

Contaminant	Soil Gas Investigation Area	Soil Gas Concentration Range $\mu\text{g}/\text{m}^3$	Samples Exceeding Environmental Comparison Value	Environmental Comparison Value ⁽¹⁾ $\mu\text{g}/\text{m}^3$
TCE	Former Molding Department ⁽²⁾	160,000 (J) – 480,000	5 of 5	150
	Remaining Areas	940 – 63,000	7 of 7	
Chloroform	All Areas	ND – 810 (J)	5 of 11	27

(1) New Jersey Department of Environmental Protection (NJDEP) – Vapor Intrusion Technical Guidance: Non-Residential Soil Gas Screening Values, March 2013

(2) Former Molding Department identified as “Area A – TCE Soil Contamination Area” (CDM 2013)

(J) - Estimated Value

ND - Not Detected

Based on the March 2013 CDM Smith remedial investigation data, the US EPA conducted additional soil gas testing on June 19, 2013. A summary of soil gas results collected below the AAI facility by the US EPA are presented in Table 2 below. A total of 16 soil gas samples, including one duplicate, were collected over a 24-hour period via Summa canisters. Samples were analyzed using US EPA Method TO-15.

Table 2: Summary of Soil Gas Contaminant Concentrations Exceeding Environmental Comparison Values – June 2013
Albea Americas, Inc. Facility
191 State Highway 31, Washington Township, Warren County, New Jersey

Contaminant	Soil Gas Investigation Area	Soil Gas Concentration Range $\mu\text{g}/\text{m}^3$	Samples Exceeding Environmental Comparison Value	Environmental Comparison Value ⁽¹⁾ $\mu\text{g}/\text{m}^3$
TCE	Former Molding Department	1,500,000 – 8,280,000	4 of 4	150
	Remaining Areas	21.5 – 486,000	10 of 12	
Tetrachloroethylene (PCE)	Former Molding Department	572 – 2,450	1 of 4	2,400
	Remaining Areas	ND – 2,160	0 of 12	

(1) New Jersey Department of Environmental Protection (NJDEP) – Vapor Intrusion Technical Guidance: Non-Residential Soil Gas Screening Values, March 2013
ND - Not Detected

Both the March 2013 and June 2013 soil gas data confirm there is significant TCE contamination below the facility acting as a source of vapor intrusion to the interior of the facility.

Indoor Air Assessment

A summary of indoor air results collected by CDM Smith on March 26, 2013 are presented in Table 3 below. A total of 11 indoor air samples, including one duplicate, were collected over a 24-hour period via summa canisters. Samples were analyzed using US EPA Method TO-15. With the exception of one sample, all remaining indoor air samples exceeded the US EPA's reference concentration (RfC)/ATSDR's Minimal Risk Level (MRL). If the substance is a known or a probable carcinogen, ATSDR's Cancer Risk Evaluation Guides (CREGs) are also considered as comparison values. All indoor air samples exceeded the ATSDR's CREGs.

The RfC is an estimate of a daily inhalation exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime of exposure. In January 2013, ATSDR adopted the US EPA's RfC as their chronic inhalation MRL. The ATSDR defines the MRL as an estimate of the daily human exposure to a hazardous substance that is likely to be without appreciable risk of adverse non-cancer health effects over a specified duration of exposure. CREGs are estimated contaminant concentrations that would be expected to cause no more than one excess cancer in a million persons exposed during their lifetime (70 years).

When assessing an exposure risk to a contaminant of concern (COC), the US EPA recommends the 95 percent upper confidence limit (95% UCL) of the arithmetic mean should be used to determine the exposure point concentrations (EPC) for site-related contaminants (US EPA 1992). For this evaluation, the 95% UCL was calculated based on TCE indoor air samples collected during one sampling event and at several areas of the facility where workers may be present during their work day.

Exposures in the facility's former molding department area (currently a storage area) were considered separately from those in the remaining areas of the facility as employees reportedly do not spend the majority of their work shift hours within this area. Additionally, the former molding department is situated directly above an area where subsurface soils are known to be highly contaminated with TCE, most likely due to historical discharges occurring in this facility area. This is further evidenced in the preceding TCE concentrations in soil gas presented in Tables 1 and 2.

To assess the potential for adverse health effects to occur to the AAI worker population, we adjusted the 95% UCL for workplace exposures then compared the adjusted 95% UCL exposure concentrations to the US EPA RfC of $2 \mu\text{g}/\text{m}^3$ as shown in Tables 3 and 4 below. The adjusted 95% UCL concentration in indoor air for both the molding department area and the remainder of the facility exceeded the RfC for TCE.

Table 3: Summary of TCE Indoor Air Contaminant Concentrations and Adjusted 95% UCL TCE Inhalation Exposure Concentration Exceeding Health-Based Comparison Value – March 2013
Albea Americas, Inc. Facility
191 State Highway 31, Washington Township, Warren County, New Jersey

Worker Exposure Assumptions ⁽¹⁾	Facility Location	TCE Indoor Air Concentration Range $\mu\text{g}/\text{m}^3$	TCE Indoor Air Concentration 95% UCL $\mu\text{g}/\text{m}^3$	<i>TCE Adjusted</i> Indoor Air Concentration 95% UCL $\mu\text{g}/\text{m}^3$	Health-Based Comparison Value ⁽²⁾ $\mu\text{g}/\text{m}^3$
12 hrs/day at 4 days/week	Former Molding Department	110 – 150	150	43	2 (RfC/MRL) 0.24 (CREG)
	Remaining Areas	4 – 180	133	38	

(1) AAI employees are assumed to have been working at the facility for at least one year.

(2) US EPA Reference Concentration (US EPA 2013a); ATSDR Minimal Risk Level (ATSDR 2013); ATSDR Cancer Risk Evaluation Guideline (ATSDR 2013)

Sample Calculation:

$$95\% \text{ UCL}_{\text{adjusted}} = 95\% \text{ UCL} \times ET \times EF$$

where 95% UCL = exposure concentration ($\mu\text{g}/\text{m}^3$);
ET = exposure time (hours/day); and
EF = exposure frequency (days/week)

$$95\% \text{ UCL}_{\text{adjusted}} = 133 \mu\text{g}/\text{m}^3 \times 12 \text{ hrs}/24 \text{ hr day} \times 4 \text{ days}/7 \text{ day week} = 38 \mu\text{g}/\text{m}^3$$

Based on the March 2013 CDM Smith remedial investigation data, the US EPA conducted two additional indoor air testing events on June 19 and 28, 2013. A summary of indoor air results from the two sampling events are presented in Table 4 below. A total of 8 indoor air samples, including one duplicate, were collected during the first sampling event and 14 indoor air samples, including one duplicate, were collected during the second sampling event. Samples were collected over a 24-hour period via summa canisters and analyzed using US EPA Method TO-15. No indoor air samples were collected from the molding department area in either of the June 2013 sampling events. Additionally, based on March 2013 indoor air data, AAI personnel had indicated to the US EPA they made adjustments to the facility's heating, ventilation, and air conditioning system (HVAC) to attempt to reduce TCE concentrations in indoor air within the facility.

Table 4: Summary of TCE Indoor Air Contaminant Concentrations and Adjusted 95%

UCL TCE Inhalation Exposure Concentration Exceeding Health-Based Comparison Value – June 2013
Albea Americas, Inc. Facility
191 State Highway 31, Washington Township, Warren County, New Jersey

June 19, 2013 Indoor Air Data – 1 st Set					
Worker Exposure Assumptions (1)	Facility Location	Indoor Air Concentration Range µg/m ³	Indoor Air Concentration 95% UCL µg/m ³	Adjusted Indoor Air Concentration 95% UCL µg/m ³	Health-Based Comparison Value ⁽²⁾ µg/m ³
12 hrs/day at 4 days/week	Former Molding Department	none collected	NE	NE	2 (RfC/MRL) 0.24 (CREG)
	Remaining Areas	1.79 – 111	78	22	
June 28, 2013 Indoor Air Data – 2 nd Set					
Worker Exposure Assumptions (1)	Facility Location	Indoor Air Concentration Range µg/m ³	Indoor Air Concentration 95% UCL µg/m ³	Adjusted Indoor Air Concentration 95% UCL µg/m ³	Health-Based Comparison Value ⁽²⁾ µg/m ³
12 hrs/day at 4 days/week	Former Molding Department	none collected	NE	NE	2 (RfC/MRL) 0.24 (CREG)
	Remaining Areas	7.82 – 599	369	105	

(1) AAI employees are assumed to have been working at the facility for at least one year.

(2) US EPA Reference Concentration (US EPA 2013a) ATSDR Minimal Risk Level (ATSDR 2013); ATSDR Cancer Risk Evaluation Guideline (ATSDR 2013)

NE – Not Evaluated

Production Well Source

AAI personnel have indicated to the US EPA they are using two on-site production wells in their operations. Groundwater from these wells is reported by facility personnel to be used for non-contact cooling water processes and to service the restrooms in the facility. There are no other disclosed uses of groundwater from these wells. The US EPA has indicated that prior sampling of groundwater from these wells show that TCE was present at concentrations of approximately 3 and 21 micrograms per liter. Facility use of this water may allow for

volatilization of TCE and, therefore, act as a potential contributing source to TCE concentrations in indoor air. Additionally, although not documented, facility personnel use of this water for drinking water or food preparation would also contribute to their exposure to TCE from ingestion exposures. AAI personnel have indicated to the US EPA that on July 10, 2013 ground water supplied to the bathrooms was terminated and city water was provided to the AAI facility bathrooms and showers.

Chemical Properties and Health Effects from Exposures to TCE

TCE is a nonflammable, colorless liquid with a somewhat sweet odor and a sweet, burning taste. It is used mainly as a solvent to remove grease from metal parts, but it is also an ingredient in adhesives, paint removers, typewriter correction fluids, and spot removers. TCE dissolves a little in water, and can remain in groundwater for a long time. It quickly evaporates from water, so it is commonly found as a vapor in the air. People can be exposed to TCE by breathing in air contaminated with TCE vapors from vapor intrusion sources and facility processes, or by drinking water that has been contaminated with TCE. Breathing small amounts of TCE may cause fetal cardiac malformations in pregnant women, decreased immune system function, headaches, lung irritation, dizziness, poor coordination, and difficulty concentrating. Regarding fetal heart malformations, animal studies have shown this health effect to be present in rats within a period of 1 to 22 gestation days (US EPA 2013a). Breathing large amounts of TCE may cause impaired heart function, unconsciousness, and death. Breathing it for long periods may cause nerve, kidney, and liver damage.

Drinking large amounts of TCE may cause nausea, liver damage, unconsciousness, impaired heart function, or death. Drinking small amounts of TCE may cause liver and kidney damage, impaired immune system function, and impaired fetal development in pregnant women, although the extent of some of these effects is not yet clear. Skin contact with TCE for short periods may cause skin rashes.

Some studies with mice and rats have suggested that high levels of TCE may cause non-Hodgkin lymphoma, as well as liver, kidney, or lung cancer. Some studies of people exposed over long periods to high levels of TCE in drinking water or in workplace air have found evidence of increased liver, kidney, and lung cancer. The most recent review of toxicological data published by the US EPA in September 2011 show fetal cardiac malformations, decreased immune system function and kidney impacts were present in animals exposed to TCE in laboratory studies. The National Toxicology Program has determined that TCE is "reasonably anticipated to be a human carcinogen," and the International Agency for Research on Cancer (IARC) has determined that trichloroethylene is "probably carcinogenic to humans."

Public Health Implications of Completed Exposure Pathways

To evaluate the health implications of exposure to TCE, we reviewed the current scientific literature for this compound. The US EPA's RfC for TCE is $2 \mu\text{g}/\text{m}^3$ and was derived from a recent toxicological review and assessment of TCE published in September 2011. Critical health endpoints used to derive and support the determination of the RfC from this toxicological assessment of TCE were used to further evaluate the severity of exposures to AAI workers. Additionally, the US EPA has determined that the RfC for TCE of $2 \mu\text{g}/\text{m}^3$ can be adjusted to account for workplace exposures. As such, the health-protective goal for the AAI facility where employees currently work 12 hour shifts, 4 days per week would be $7 \mu\text{g}/\text{m}^3$ ($2 \mu\text{g}/\text{m}^3 = x \mu\text{g}/\text{m}^3 \times 12 \text{ hours}/24 \text{ hour day} \times 4 \text{ days}/7 \text{ day week}$). (US EPA, Personal Communication to Glenn Pulliam, NJDOH July 17, 2013).

The US EPA recommends that health risk assessors not use the Occupational Safety and Health Administration (OSHA) workplace standards to evaluate the health risk from vapor intrusion where the vapor intrusion has been identified in commercial/industrial settings and where the chemicals of concern for the vapor intrusion pathway are not used in the work place (US EPA 2012).

Non-Cancer Health Effects

Inhalation of TCE in Indoor Air

The US EPA identified two animal studies as the basis of the Reference Concentration (RfC) for non-cancer effects (US EPA 2011b). In these studies, where animals were exposed to TCE orally via drinking water, the most sensitive adverse effects involved the immune system and the developing fetus (Johnson et al. 2003, Keil et al. 2009). The US EPA used physiologically based pharmacokinetic (PBPK) modeling to convert the oral dose in animals to a human equivalent concentration (HEC) of TCE in air (US EPA 2011a). In addition, for one rat study, US EPA used the lower confidence limit of the benchmark dose response (BMDL01) to model (i.e., estimate) the air concentration that would yield a one percent response rate for fetal cardiac malformations. The result of these transformations is an HEC99, BMDL01 of $21 \mu\text{g}/\text{m}^3$. The HEC99 is the human exposure concentration for which there is a 99% likelihood that a randomly selected individual will have an internal dose less than or equal to, in this case, the BMDL01. To summarize, the US EPA predicts that there is a small risk of fetal heart malformations for pregnant women exposed to TCE at $21 \mu\text{g}/\text{m}^3$. The US EPA used an uncertainty factor of 10 to obtain the RfC of $2 \mu\text{g}/\text{m}^3$ (ATSDR 2012; US EPA 2013a).

A recently released epidemiologic study concluded that maternal residence in areas of soil vapor intrusion of TCE into indoor air was associated with fetal cardiac defects (Forand et. al., 2011). Although the study did not evaluate a dose-response relationship, it does support the use of the animal studies for the RfD/RfC.

US EPA also used a 30-week mouse study and identified a lowest observed adverse effect level (LOAEL) for decreased thymus weight as the health endpoint. PBPK modeling was used to derive $190 \mu\text{g}/\text{m}^3$ as the HEC99, LOAEL. This concentration was divided by an uncertainty factor of 100 to derive the RfC (ATSDR 2012).

The US EPA also cites a third study (of lower confidence) in support of the RfC where female rats were exposed to TCE by administering the chemical in corn oil by gavage for a 104 week period (NTP 1988). The US EPA used PBPK modeling to convert the oral dose in animals to a HEC of TCE in air (US EPA 2013a). US EPA used the lower confidence limit of the BMDL05 to model (i.e., estimate) the air concentration that would yield a five percent response rate resulting in toxic nephropathy. The result of these transformations is an HEC99, BMDL05 of $30 \mu\text{g}/\text{m}^3$. The HEC99 is the human exposure concentration for which there is a 99% likelihood that a randomly selected individual will have an internal dose less than or equal to, in this case, the BMDL05. To summarize, the US EPA predicts that there is a 5% risk of kidney damage to individuals with long term exposure to TCE at $30 \mu\text{g}/\text{m}^3$ (US EPA 2013a).

To assess the severity of exposures and the degree to which workers within the facility may develop adverse health effects from inhalation exposures to TCE we compared the adjusted 95% UCL exposure concentrations and the adjusted maximum TCE exposure concentrations to the LOAELs from the previously described studies (Johnson et al. 2003, Keil et al. 2009).

TCE concentrations in indoor air exceeded the LOAEL of $21 \mu\text{g}/\text{m}^3$ based on March and June 2013 sampling data adjusted for workplace exposure duration as presented in Table 5 on the following page.

If no measures are taken to mitigate vapor intrusion and the adjusted exposure point concentrations of TCE in indoor air are not reduced to levels to protect public health, pregnant workers, as well as any women of child-bearing age who become pregnant while employed at this facility, are at risk for fetal heart malformations to occur to their children.

Adjusted exposure point concentrations of TCE in indoor air were below the LOAEL of $190 \mu\text{g}/\text{m}^3$ in the molding department area and the remainder of facility areas. However, because the adjusted exposure point concentrations are approaching the LOAEL of $190 \mu\text{g}/\text{m}^3$, facility workers may be at risk for developing adverse health effects including damage to the immune system from reduced thymus weight.

Additionally, the US EPA cites the 1988 study conducted by the NTP in support of their RfC for TCE where they have determined that humans exposed to TCE in air at $30 \mu\text{g}/\text{m}^3$ are at risk of developing kidney damage. As the adjusted exposure point concentrations for TCE in indoor air exceed $30 \mu\text{g}/\text{m}^3$, facility workers may be at risk for developing kidney damage from inhalation exposures.

Table 5: Comparison of Adjusted 95% UCL and Adjusted Maximum TCE Inhalation Exposure Concentration to Health Endpoints from Toxicological Studies
Albea Americas, Inc. Facility
191 State Highway 31, Washington Township, Warren County, New Jersey

Worker Exposure Assumptions ⁽¹⁾	Facility Location	Adjusted 95% UCL to Adjusted Maximum TCE Indoor Air Concentration $\mu\text{g}/\text{m}^3$ ⁽²⁾	Increased Risk of Adverse Effect	
			Study 1: Fetal Heart Malformations (LOAEL 21 $\mu\text{g}/\text{m}^3$) Support Study 3: Toxic Nephropathy (LOAEL 30 $\mu\text{g}/\text{m}^3$)	Study 2: Adult Immunological Effects (LOAEL 190 $\mu\text{g}/\text{m}^3$)
March 2013 Indoor Air Data				
12 hrs/day at 4 days/week	Former Molding Department	43	Yes	Yes
	Remaining Areas	38 - 51	Yes	Yes
June 2013 Indoor Air Data – 1 st Data Set				
12 hrs/day at 4 days/week	Former Molding Department	NE	NE	NE
	Remaining Areas	22 - 32	Yes	Yes
June 2013 Indoor Air Data – 2 nd Data Set				
12 hrs/day at 4 days/week	Former Molding Department	NE	NE	NE
	Remaining Areas	105 - 171	Yes	Yes

(1) AAI employees are assumed to have been working at the facility for at least one year.
(NE) Not evaluated due to lack of data

- (2) Values presented to demonstrate the range of inhalation exposure concentrations to which workers may be subjected.

Sample Calculation- Adjusted Maximum:

$$\text{Maximum TCE Concentration}_{\text{adjusted}} = \text{Maximum TCE Conc.} \times \text{ET} \times \text{EF}$$

where Maximum TCE Conc. = Maximum Detected TCE Concentration ($\mu\text{g}/\text{m}^3$);
ET = exposure time (hours/day); and
EF = exposure frequency (days/week)

$$\text{Maximum TCE Conc.}_{\text{adjusted}} = 180 \mu\text{g}/\text{m}^3 \times 12 \text{ hrs}/24 \text{ hr day} \times 4 \text{ days}/7 \text{ day week} = 51 \mu\text{g}/\text{m}^3$$

Cancer Health Effects

The Department of Health and Human Services, National Toxicology Program classifies TCE as reasonably anticipated to be a human carcinogen. In humans, occupational exposure to TCE was associated with excess incidences of several cancers, particularly liver cancer, non-Hodgkin lymphoma, and kidney cancer (NTP 2011). Animal studies showed that TCE exposure caused tumors in mice and rats at several different sites, including liver and kidney, by inhalation or oral exposure (NTP 2011). The International Agency for Research on Cancer (IARC) has determined that TCE is a probable human carcinogen based on epidemiological studies showing increased rates of liver cancer and non-Hodgkin lymphoma, primarily in workers who were exposed to TCE on the job, and animal studies showing increased numbers of liver and kidney tumors upon oral administration. The US EPA characterizes TCE as carcinogenic to humans by all routes of exposure (US EPA 2011). This conclusion is based on human epidemiology studies showing associations between human exposure to TCE and kidney cancer, non-Hodgkin lymphoma, and liver cancer.

The site-specific lifetime excess cancer risk (LECR) indicates the cancer potential of contaminants. LECR estimates are usually expressed in terms of excess cancer cases in an exposed population in addition to the background rate of cancer. For perspective, the lifetime risk of being diagnosed with cancer in the United States is 46 per 100 individuals for males, and 38 per 100 for females; the lifetime risk of being diagnosed with any of several common types of cancer ranges between 1 in 10 and 1 in 100 (ACS 2011). Typically, health guideline CVs developed for carcinogens are based on one excess cancer case per 1,000,000 individuals. The NJDOH considers estimated cancer risks of less than one additional cancer case among one million persons exposed as insignificant or no increased risk (expressed exponentially as 10^{-6}).

Based on our evaluation, using the US EPA's Inhalation Unit Risk Factor ($4.1 \times 10^{-6} \mu\text{g}/\text{m}^3)^{-1}$ and the adjusted exposure point concentrations of TCE in indoor air, the range of LECRs were estimated to be approximately 4 in 1,000,000 to 6 in 1,000,000 for employees working at the AAI facility since it was acquired in 2010, which is considered no apparent increased risk when compared to the background risk of all or specific cancers. However, this cancer risk assessment would be underestimated if AAI employees were also employed by the

previous owners, PPPI, and worked within this facility during their term of employment where inhalation exposures to TCE in indoor air are assumed to have been similar and thus would have increased their exposure duration.

Conclusions and Recommendations

Based on the review of data available through June 2013, the ATSDR and NJDOH categorize the current and future use of the AAI facility as a **public health hazard** due to the presence of elevated concentrations of TCE in the air within the facility. Workers in the AAI facility have been exposed to TCE through inhalation of contaminated indoor air due to vapor intrusion from contaminated sub-surface media. Based on the concentrations of TCE in indoor air, the extent of exposure would place pregnant women and women of child bearing age who become pregnant while employed at the facility at a higher risk for fetal heart malformations to occur to their children. All employees working within the AAI facility are being placed at a higher risk for health effects from inhalation exposures to TCE for both damage to the immune system from reduced thymus weight and for kidney damage based on US EPA supporting documentation.

Based on these findings, as well as acknowledging that certain interim measures have been implemented at the AAI facility, the NJDOH recommends the following:

1. Continue to take immediate steps to stop or reduce inhalation and possible ingestion exposures to TCE to a level that does not pose a health concern for all employees within the AAI facility. The ATSDR and NJDOH consider the US EPA's adjusted health-protective goal of $7 \mu\text{g}/\text{m}^3$ for TCE in indoor air to be protective of public health for all AAI employees at this facility.²
2. Remediation measures should continue to be implemented as soon as feasible to reduce to below health concerns or remove the threat of vapor intrusion of TCE and other elevated soil gas contaminants. Remedial measures are immediately required as soil gas concentrations of TCE below this structure are significantly elevated and are impacting indoor air at concentrations that pose an unacceptable health risk to workers.
3. Additional indoor air sampling needs to be performed to monitor concentrations of contaminants in indoor air after the implementation of vapor intrusion mitigation

² EPA has determined that the RfC for TCE of $2 \mu\text{g}/\text{m}^3$ can be adjusted to account for workplace exposures. As such, the health-protective goal for the AAI facility where employees currently work 12 hr shifts, 4 days per week would be $7 \mu\text{g}/\text{m}^3$ ($2 \mu\text{g}/\text{m}^3 = X \mu\text{g}/\text{m}^3 \times 12 \text{ hrs}/24 \text{ hr day} \times 4 \text{ days}/7 \text{ day week}$) (US EPA, Personal Communication to Glenn Pulliam, NJDOH July 17, 2013).

measures. This needs to be completed to ensure TCE concentrations in indoor air do not pose a health concern for TCE inhalation exposures to AAI facility workers.

4. Based on concentrations observed in soil gas below the AAI facility, the US EPA should review all soil gas and indoor air investigation data for the area immediately surrounding the facility to ensure all potential vapor intrusion receptors have been evaluated.

The NJDOH is not recommending biological testing since the results would not have any clinical relevance to individual workers; however workers wishing to discuss health concerns related to TCE exposure may contact the Rutgers Environmental and Occupational Health Sciences Institute (EOHSI) at 848-445-0123. The EOHSI clinic has physicians specializing in environmental and occupational medicine.

The NJDOH and ATSDR are available to review any additional data at the request of the US EPA and provide further guidance as appropriate. The NJDOH and ATSDR are also available to assist the NJDEP and the US EPA in communicating the health risks to the facility owner and workers.

If you have any questions regarding the findings presented in this letter, please contact me at 609-826-4920 or by email at Joe.Eldridge@doh.state.nj.us.

Sincerely,

A handwritten signature in blue ink, appearing to read "Joe Eldridge".

Joseph Eldridge, M.P.H.
Director
Consumer, Environmental & Occupational
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c: Gregory V. Ulirsch, Leah Graziano, Elena Vaouli ATSDR
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REPORT PREPARATION

This Letter Health Consultation for the Pohatcong Valley Groundwater Contamination Superfund site (Albea Americas Facility), Warren County, New Jersey, was prepared by the New Jersey Department of Health under a cooperative agreement with the federal Agency for Toxic Substances and Disease Registry (ATSDR). It is in accordance with the approved agency methods, policies, procedures existing at the date of publication. Editorial review was completed by the cooperative agreement partner. ATSDR has reviewed this document and concurs with its findings based on the information presented. ATSDR's approval of this document has been captured in an electronic database, and the approving agency reviewers are listed below.

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